K091141
Amended
9/21/11

510 (k) Summary
Safety and Effectiveness Men's Trouser Socks and Women's Trouser Socks

510(K) Number K091141
Device Name: Therafirm Men's Trouser Socks and Women's Trouser Socks
Indications for Use: Help prevent edema and leg discomfort and help prevent deep vein thrombosis for long distance travelers
Over-The-Counter Use

Classification Name: Medical Support Stocking (21 CFR 880.5780, Product Code DWL

This submission covers the indication for compression stockings in the 15-20 mmHg range, such as the Therafirm gradient compression trouser socks (including same products offered for OEM applications), help prevent edema and leg discomfort, and help prevent deep vein thrombosis, especially for long distance travelers. These products fall under the device classification of medical support stockings (21 CFR 880.5780), Class II medical device, Product Code DWL. Knit-Rite's Therafirm division manufactures Men's Trouser Socks and Women's Trouser Socks that fall in to this category, and they are substantially equivalent to Jobst Travel Socks (K032325) and SSL Americas Flight Sock (K040353).

Therafirm Trouser Socks and their substantial equivalents are knit on circular knit machines. These products are made with nylon and spandex; however some Therafirm Trouser Socks contain Coolmax/Lycra for the wearer's comfort. Therafirm Trouser Socks and their substantial equivalents provide similar compression at the ankle, are sized based on ankle and calf circumferences, and include shoe sizes as a helpful reference.

The controlled gradient compression provided in both of these substantially equivalent products, starting with more compression circumferentially at the ankle and gradually decreases up to the proximal end helps reduce capillary leakage, prevent pooling of blood, and improve blood flow.

The products being submitted are substantially equivalent to the predicate product in material content, function and indication and as such can be considered as safe and effective as the referenced, predicate product.

This statement is to assure that Therafirm Trouser Socks are safe and effective when worn for their intended purpose and fit properly according to the guidelines.

See Section on Performance Testing – Bench and Exhibits on pages 40 – 43 for nonclinical testing that demonstrates that the device is safe, effective, and performs in comparison to predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeffrey C. Dalbey
Director of R & D
Knit-Rite, Incoporated
Therafirm Hosiery Company
126 Mill Street
Ellerbe, North Carolina 28338

JUL 24 2009

Re: K091141
Trade/Device Name: Therafirm Anit-Embolism Stockings, Therafirm Men's Trouser Socks and Women's Trouser Socks
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: July 2, 2009
Received: July 6, 2009

Dear Mr. Dalbey :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

U.S. Department of Health & Human Services

Indications for Use Form

510(k) Number (if known): **K091141**

Device Name: **Therafirm Anti-Embolism Stockings**

Indications for Use: **Help prevent edema and leg discomfort, and help prevent deep vein thrombosis in individuals subjected to immobility.**

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K091141